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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|------------------------|------------------|
| 10/081,817 | 02/22/2002 | Kornelia Polyak | 00530-094001/ DFCI#689 | 3070 |

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225 FRANKLIN ST
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EXAMINER

NICKOL, GARY B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1642 | 13 |

DATE MAILED: 03/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| <i>Office Action Summary</i> | Application No. | Applicant(s) |
|-------------------------------------|------------------------|---------------------|
| | 10/081,817 | POLYAK ET AL. |
| Examiner | Art Unit | |
| Gary B. Nickol Ph.D. | 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 21 January 2003 .

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-34 is/are pending in the application.
4a) Of the above claim(s) 1-22 and 25-34 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 23 and 24 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8,11 .
4) Interview Summary (PTO-413) Paper No(s). ____ .
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____ .

DETAILED ACTION

The Election filed January 21, 2003 (Paper No. 12) in response to the Office Action of December 16, 2002 is acknowledged and has been entered. Applicant has elected Group X (Claims 23-24) without traverse.

Claims 1-34 are pending.

Claims 1-22, and 25-34 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 23-34 are currently under consideration.

Specification

The specification is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (i.e. see page 14, line 20). Applicant is requested to delete all embedded hyperlinks and/or other form of browser-executable codes. See MPEP § 608.01

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23-24 are rejected as vague and indefinite for reciting the term HIN-1 in association with a promoter region as the sole means of identifying said region. The use of laboratory designations only to identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules and or regions. The rejection can be obviated by amending the claims to specifically and uniquely identify the HIN-1 promoter region, for example, by SEQ ID NO.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-24 rejected under 35 U.S.C. 102(b) as being anticipated by Baylin *et al.* (US Patent No. 5,922,590, July 13, 1999).

The claims are drawn to a method of diagnosis comprising providing a test cell and determining the degree of methylation of a HIN-1 promoter region in the test cell, wherein a high degree of methylation of the HIN-1 promoter region is an indication that the test cell is a cancer cell; wherein the test cell is a breast cell.

Due to the indefiniteness of the claim language as set forth above, a "HIN-1 promoter region" is interpreted as encompassing any polynucleotide sequence including genes.

Baylin *et al.* teach a method of diagnosis comprising providing a test cell and determining the degree of methylation of a HIN-1 promoter region in the test cell, wherein a high degree of methylation of the HIN-1 promoter region is an indication that the test cell is a cancer cell; wherein the test cell is a breast cell (see column 12, lines 24-67).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

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March 28, 2003

Granthibai